APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,593	12/08/2003	Samuel I. Brandt	2002P20031 US01	2121

7590   04/16/2009

Alexander J. Burke
Intellectual Property Department
5th Floor
170 Wood Avenue South
Iselin, NJ 08830

EXAMINER
WOODS, TERESA S

ART UNIT	PAPER NUMBER
3686	

MAIL DATE	DELIVERY MODE
04/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

     4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

     a)☐ All   b)☐ Some * c)☐ None of:

         1.☐ Certified copies of the priority documents have been received.

         2.☐ Certified copies of the priority documents have been received in Application No. _____.

         3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

     * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
     Paper No(s)/Mail Date *20031208 and 20050527* .

4) ☐ Interview Summary (PTO-413)
     Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____ .

DETAILED ACTION

Status of Claims

1.   This action is in reply to the application filed on 12/08/2003.

2.   Claims 1-16 are currently pending and have been examined.

Claim Rejections - 35 USC § 102

3.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign
country or in public use or on sale in this country, more than one year prior to the
date of application for patent in the United States.

4.   Claims 1-16 are rejected under 35 U.S.C. 102(b) as being unpatentable by

McIlroy (US 5,583,758 A).

5.   **Claim 1:**

McIlroy, as shown below, discloses the following limitation:

- a data processor for identifying a potential change in use of a particular
  treatment by (see at least Fig. 1, column 4, lines 50-60, column 6, lines 1-9)

McIlroy's CPU serves as a data processor in figure 1. Also, the second citation
explains the analysis of patient medical treatment.

- examining data representing a plurality of orders generated over a particular
  time period and used in treating a plurality of patients, to identify a number of
  orders initiating application of a particular treatment to individual patients of

said plurality of patients to address a particular medical condition and (see at least Fig. 26, column 18, lines 33-58)

- determining at least one of, (a) whether said number of orders exceeds a predetermined threshold and (b) whether a rate of change in said number of orders relative to a previously determined number of orders is significant; and (see at least column 18, lines 16-25)

- a message processor for initiating generation of a message to alert a message recipient of an identified potential change in use of said particular treatment (see at least Fig. 1, Fig. 14, column 12, lines 36-45).

In McIlroy's figure 1, the central processing unit encapsulates treatment questions that lead to alerting user messages.

6. **Claim 2:**

McIlroy, as shown below, discloses the following limitation:

- an acquisition processor for acquiring data representing said plurality of orders used in treating said plurality of patients and for associating an individual order with at least one of, a) said particular medical condition and (b) a set of medical conditions including said particular medical condition (see at least Fig. 1, Fig. 10, Fig. 11, Fig. 12a, column 11, lines 6-34).

McIlroy's CPU serves as a data processor in figure 1. Here, medical categories are medical conditions of a patient and they are collected using McIlroy's computer program. Also, orders and plurality of orders are represented by diagnosis codes, which are pointed out in figure 12a.

7. **Claim 3:**

McIlroy, as shown below, discloses the following limitation:

- an acquisition processor for acquiring data identifying a plurality of medical conditions exhibited by an individual patient and for applying said data identifying said plurality of medical conditions exhibited by said individual patient in associating said individual order with said at least one of, (a) said particular medical condition and (b) a set of medical conditions including said

particular medical condition (see at least Fig. 10, Fig. 11, column 11, lines 6-18).

Again, McIlroy's processor has the ability to collectively acquire medical conditions for medical patients.

8.   **Claim 4:**

McIlroy, as shown below, discloses the following limitation:

- wherein said acquisition processor derives data identifying said plurality of medical conditions and potentially associated sub-conditions, wherein a potentially associated sub-condition of a medical condition is identified using a clinical knowledge model that associates medical conditions based upon one of potential etiology, potential complication, clinical associations, and a combination thereof (see at least Fig. 9a, column 9, line 5 to column 10, line 23).

McIlroy's chart outlining the guideline development process serves as the clinical knowledge model that considers a multitude of scientific support.

9.   **Claim 5:**

McIlroy, as shown below, discloses the following limitation:

- wherein said data identifying said plurality of medical conditions exhibited by said individual patient is acquired from a stored patient record (see at least Fig. 9b, Fig. 10, Fig. 11, column.

Figure 9b shows the process to entering a patient's medical record, while the plurality of medical conditions are stored and displayed in figures 10 and 11.

10.   **Claim 6:**

McIlroy, as shown below, discloses the following limitation:

- wherein said potential change in use of said particular treatment comprises at least one of, (a) a change in frequency of use of said particular treatment by physicians to treat said particular medical condition and (b) a change in type

of medical condition treated with said particular treatment (see at least Fig. 16, Fig. 24B, column 18, lines 12-15).

In both figures, McIlroy's care change option serve as a change in medical condition treatments.

11. **Claim 7:**

McIlroy, as shown below, discloses the following limitation:

- wherein said data processor correlates data representing a particular order of said plurality of orders with at least one of, (a) said particular medical condition, (b) another order of said plurality of orders and (c) a documentation template used for initiating an order (see at least Fig. 15, column 12, lines 36-47).

Figure 15 serves a software documentation template that has the option to correlated collected medical treatment case information.

12. **Claim 8:**

McIlroy, as shown below, discloses the following limitation:

- wherein said data processor performs said correlation using at least one of, (i) cluster analysis, 25 (ii) best fit analysis and (iii) a statistical correlation technique (see at least column 7, lines 35-40).

Here, the clinical decision data collection component is used to perform statistical correlation techniques.

13. **Claim 9:**

McIlroy, as shown below, discloses the following limitation:

- wherein said message processor initiates generation of a message prompting a user with a suggestion of at least one of, (a) an additional order item to be added to an existing order set documentation template and (b) a deletion of

an order item from an existing order set documentation template (see at least Fig. 15, column 12, lines 36-47).

Figure 15 displays the addition of multiple treatment options. The specialist review screen is the means for messaging and prompting a user.

14. **Claim 10:**

McIlroy, as shown below, discloses the following limitation:

- wherein a second message is received in response to said message alert and said second message initiates at least one of, (a) an addition of an order item to an existing order set documentation template and (b) a deletion of an order item from an existing order set documentation template (see at least Fig. 15, column 12, lines 36-47, 13, lines 42-47).

Here, there are two instances where message alerts within this documentation template.

15. **Claim 11:**

McIlroy, as shown below, discloses the following limitation:

- wherein an acquisition processor for acquiring data identifying a plurality of medical conditions exhibited by an individual patient and (see at least Fig. 10, Fig. 11, column 11, lines 6-18).

- applying said data identifying said plurality of medical conditions exhibited by said individual patient in associating said individual order with said at least one of, (a) said particular medical condition and (b) a set of medical conditions including said particular medical condition (see at least Fig. 1, Fig. 10, Fig. 11, Fig. 12a, column 11, lines 6-34).

McIlroy's CPU serves as a data processor in figure 1. Here, medical categories are medical conditions of a patient and they are collected using McIlroy's computer program. Also, orders and plurality of orders are represented by

diagnosis codes, which are pointed out in figure 12a.

16. **Claim 12:**

McIlroy, as shown below, discloses the following limitation:

- wherein said data processor monitors data representing orders to identify said data representing said plurality of orders for examining based on at least one of, (i) a predetermined particular order item in an order set, (ii) a predetermined particular order documentation template, (iii) a source of a predetermined particular order and (iv) a predetermined particular medical condition likely to be associated with an order (see at least Fig. 10, Fig. 11, column 11, lines 6-18).

Here, McIlroy's predefined medical categories in figures 10 and 11 serve as a predetermined particular order documentation template.

17. **Claim 13:**

McIlroy, as shown below, discloses the following limitation:

- a data processor for identifying a potential change in use of a particular treatment by (see at least Fig. 1, column 4, lines 50-60, column 6, lines 1-9),
-
- examining data representing a plurality of orders generated over a particular time period and used in treating a plurality of patients, to identify a number of orders initiating application of a particular treatment to individual patients of said plurality of patients to address a particular medical condition and (see at least Fig. 26, column 18, lines 33-58)

- determining whether a change in said number of orders relative to a previously determined number of orders is significant, and (see at least column 18, lines 16-25)

- prompting a user with a suggestion of at least one of, (a) an additional order item to be added to an existing order set documentation template and (b) a deletion of an order item from an existing order set documentation template (see at least Fig. 15, column 12, lines 36-47).

Figure 15 displays the addition of multiple treatment options. The specialist review screen is the means for messaging and prompting a user.

18.   **Claim 14:**

McIlroy, as shown below, discloses the following limitation:

- an acquisition processor for acquiring data representing said plurality of orders used in treating said plurality of patients and for associating an individual order with at least one of (a) said particular medical condition and (b) a set of medical conditions including said particular medical condition (see at least Fig. 1, Fig. 10, Fig. 11, Fig. 12a, column 11, lines 6-34);

- a data processor for identifying a potential change in use of a particular treatment by, examining data representing a plurality of orders associated with a particular medical condition and generated over a particular time period and used in treating a plurality of patients, to identify a number of orders initiating application of a particular treatment to individual patients of said plurality of patients and (see at least Fig. 26, column 18, lines 33-58)

- determining whether a change in said number of orders relative to a previously determined number of orders is significant; and (see at least column 18, lines 16-25)

- a message processor for initiating generation of a message to alert a message recipient of an identified potential change in use of said particular treatment (see at least Fig. 1, Fig. 14, column 12, lines 36-45) .

19.   **Claim 15:**

McIlroy, as shown below, discloses the following limitation:

- examining data representing a plurality of orders generated over a particular time period and used in treating a plurality of patients, to identify a number of orders initiating application of a particular treatment to individual patients of said plurality of patients to address a particular medical condition and (see at least Fig. 26, column 18, lines 33-58)

- determining at least one of, (a) whether said number of orders exceeds a predetermined threshold and (b) whether a rate of change in said number of

orders relative to a previously determined number of orders is statistically significant; and (see at least column 18, lines 16-25)

- initiating generation of a message to alert a message recipient of an identified potential change in use of said particular treatment (see at least Fig. 1, Fig. 14, column 12, lines 36-45).

20. **Claim 16:**

McIlroy, as shown below, discloses the following limitation:

- said determining step determines at least one of, (a) whether said number of orders exceeds a predetermined threshold and (b) whether a rate of change in said number of orders relative to a previously determined number of orders is statistically significant (see at least column 18, lines 16-25).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Teresa Woods** whose telephone number is **571.270.5509.** The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **Jerry O'Connor** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

or faxed to **(571) 273-8300**.

Hand delivered responses should be brought to the **United States Patent**

and Trademark Office Customer Service Window:

Randolph Building
401 Dulany Street
Alexandria, VA 22314.

/T. W./
Patent Examiner, Art Unit 4114
04/09/09

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686